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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,307	07/22/2004	Roberto Burioni	937-PCT-US	9195

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,307	BURIONI, ROBERTO	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3 and 12-29 are pending in the application.

2. In the prior action, mailed on March 2, 2007. claims 1-3 and 12-29 were pending, with claims 1-3, 27, and 28 under consideration and rejected; and claims 12-26, and 29 withdrawn from consideration.

In the Response of August 15, 2007, the Applicant cancelled claims 1-3 and 12-29, and added new claims 30-39.

3. Claims 30-39 are under consideration.

Sequence Listing

4. **(Prior Objection- Maintained)** The specification and claims were objected to for containing referring to sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). The claims have been amended to refer to the sequence identification numbers. However, the specification (see e.g., pages 3, 4, and 8-12) has not been so amended. The objection is therefore maintained.

Claim Rejections - 35 USC § 101

5. **(Prior Rejection- Withdrawn)** Claims 1, 27, and 28 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In view of the amendment of the claims to read on compositions comprising isolated antibodies, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(Prior Rejection- Withdrawn)** Claims 1-3, 27, and 28 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims were rejected on two grounds. First, the claims were rejected because it was not clear what was meant by reference to the antibody of e137 or e301, as these are not antibody but artificially created Fab fragments. In view of the amendments to the claims, this portion of the rejection is withdrawn.

The claims were also rejected on the ground that it was not clear what was meant by reference to a human antibody comprising the sequences of the e137 and e301 Fabs. In view of the amendment of the claims such that they no longer refer to e137 or e301 as human antibodies, and the teachings on page 6 (lines 6-8, referencing reference [9]) the recombinant production of human antibodies comprising the variable domains of e137 and e301, this portion of the rejection is also withdrawn.

8. **(New Rejection- Necessitated by Amendment)** Claims 34 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the limitation "the human antibody." There is insufficient antecedent basis for this limitation in

these claims, or in claims 30 and 32, the claims from which claims 34 and 36, respectively, depend.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. **(Prior Rejection- Maintained)** Claim 27 was rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions for inhibiting HCV E2 binding to a cell (i.e. having neutralizing activity), does not reasonably provide enablement for compositions for anti-HCV therapy comprising such neutralizing antibodies. This claim has been cancelled, and replaced by new claims 30-39, each of which includes the intended use limitation requiring in vivo therapeutic efficacy.

In traversal of the rejection, the Applicant asserts that they have presented data demonstrating that the e137 and e301 antibodies are neutralizing antibodies capable of inhibiting viral infection, and that the claims are therefore enabled. This argument is not found persuasive for the reasons of record (indicating that the mere identification of an antibody as neutralizing antibody does not mean that those in the art would be capable of using such in anti-HCV therapies. Moreover, it is noted that the application itself states that the data presented confirms "that even antibodies inhibiting E2 binding may fail to prevent viral infection." Page 16, lines 10-12. In view of the above, and because the Applicant has presented no evidence that the claimed antibodies are effective anti-HCV therapeutics, the rejection is maintained.

It is suggested that the claims be amended to read on compositions comprising the indicated antibodies, without reference to an intended use.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **(Prior Rejection- Maintained)** Claims 1, 27, and 28 were rejected under 35 U.S.C. 102(b) as being anticipated by Burioni et al. (Hepatology 28:810-14).These claims have been cancelled, and replaced by claims 30-33, 38, and 39.

The Applicant traverses the rejection on the basis that the reference fails to provide any in vivo information. This argument is not found persuasive. The present claims are not drawn to a method, but to a composition with an intended use. The presence of the intended use is insufficient to overcome a anticipation rejection where the compositions of the claims and those disclosed in the reference are otherwise identical. See e.g., MPEP 2111.02 II (stating in part "If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim."). Because there does not appear to be any structural difference between the claimed compositions and those of the prior art, the rejection is maintained.

13. **(Prior Rejection- Withdrawn)** Claims 1, 27, and 28 were rejected under 35 U.S.C. 102(b) as being anticipated by Habersetzer et al. (Virology 249: 32-41). In view of the

amendment to the claims such that the pending claims are limited to antibodies and fragments thereof comprising the variable domain sequences of Fabs e137 and e301, this rejection is withdrawn.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **(Prior Rejection- Maintained)** Claims 1-3, 27, and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Burioni as applied to claims 1, 27, and 28, further in view of the teachings of Poul et al. (Immunotechnology 1: 189-96) and Foung et al. (U.S. 7,091,324). These claims have been cancelled and replaced by new claims 30-39.

In traversal of this rejection, the Applicant asserts that they have shown unexpected results in the neutralizing properties of the e137 and e301 Fabs. However, it is noted that in order to show unexpected results, the Applicant must show that the claimed invention has unexpected results over the "closest prior art." See e.g., MPEP 716.02(e). In the present case, the closest prior art discloses the e137 and e301 Fabs. Because the prior art and the claimed invention both comprise these Fabs, and as the antibodies comprising the variable domains of these Fabs would have been expected to have the same functional characteristics as the Fabs, the Applicant has not shown that the claimed invention has unexpected properties over the prior art. At best, the Applicant has shown a new or previously unrecognized property of the Fabs of the prior art,

neither of which is sufficient to overcome the rejection. See e.g., MPEP §§ 2112 I and 2145 II. The Applicant's argument is therefore not found persuasive.

It is noted that claims 34-37 require that the full size antibody is an IgG1 molecule. The teachings of Burioni teach the making of artificial Fabs of the IgG1 isotype. See, page 33. Further, the teachings of Foung also teach the use of antibodies of the IgG1 isotype. See e.g., cols 4 (Table 3) and 44 (lines 48-52). It would therefore have been obvious to those of ordinary skill in the art to make full-length antibodies of this isotype from the disclosed variable regions. The making of such was known in the art. It is noted that other teachings in the art support the indication that those of ordinary skill in the art would be able to construct full-length IgG1 antibodies from the variable domains disclosed by Burioni. See e.g., Boel et al., J Immunol Methods 239: 153-66. Thus, these claims fail to describe a patentable invention over the prior art.

Double Patenting

16. **(New Warning)** Applicant is advised that should claims 35 and/or 37 be found allowable, claims 34 and/or 36, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648